James R. Condo (#005867)
Amanda C. Sheridan (#027360)
SNELL & WILMER L.L.P.
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, AZ 85004-2204
Telephone: (602) 382-6000
jcondo@swlaw.com
asheridan@swlaw.com

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
NELSON MULLINS RILEY & SCARBOROUGH LLP
Atlantic Station
201 17th Street, NW, Suite 1700
Atlanta, GA 30363
Telephone: (404) 322-6000
richard.north@nelsonmullins.com
matthew.lerner@nelsonmullins.com

Attorneys for Defendants
C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation, LISA HYDE and MARK HYDE, a married couple, Plaintiffs, v. C. R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, INC., an Arizona corporation, Defendants.	No. 2:15-MD-02641-DGC **DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT AS TO PLAINTIFFS LISA AND MARK HYDE'S CLAIMS** (Assigned to the Honorable David G. Campbell) **(Oral Argument Requested)**

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

In their Response, Plaintiffs discuss numerous internal Bard documents and deposition testimony, which appear to have no bearing on Bard's Motion and/or are taken out of context.[1] At the same time, Plaintiffs entirely ignore the following grounds on which Bard moved for summary judgment, despite refusing to withdraw the claims during pre-motion meet-and-confer discussions:

- That the sophisticated user doctrine relieves Bard of any duty to warn;
- Plaintiffs' failure to identify a reasonable alternative warning;
- Plaintiffs' failure to prove that a different warning would have prevented her alleged injuries;
- That Wisconsin law does not recognize breach of implied warranty claims in products liability cases; and
- That Wisconsin law does not recognize failure to recall/retrofit as an independent cause of action.

Plaintiffs also fail to address nearly all of the case law that Bard cited in support of its arguments, including, for example, cases finding that manufacturers have no duty to warn about comparative rates of complications. Finally, Plaintiffs argue several of their legal positions without citation to any legal authority, such as that a different product can serve as a reasonable alternative design and that fraud on the FDA satisfies the reliance element of their misrepresentation and concealment claims.

For these reasons, and as discussed more fully below and in Bard's Motion, the Court should grant summary judgment on Plaintiffs' claims.

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[1] As part of their response papers, Plaintiffs filed a 52-page "Omnibus Separate Statement of Facts" (Doc. 7950). The District of Arizona Local Rule 56.1(b) does not require a moving party to reply to a "controverting statement of facts" or respond to a non-moving party's "additional facts." Accordingly, Bard is not filing such a reply or response here. As noted throughout this Reply Brief, however, these allegations do not raise a genuine issue of material fact that would preclude summary judgment. Instead, Plaintiffs' reference to these allegations appear to be largely an attempt to "pack" the summary judgment record with irrelevant allegations (e.g., allegations about filters that Plaintiff did not receive). To be clear, Bard disagrees with Plaintiffs' characterization of many of these alleged "facts," even if such disagreement does not raise a genuine issue of material fact.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

A. Plaintiffs Apply the Incorrect Choice of Law Test in Arguing that Nevada Law Should Apply; When Using the Correct Test, Wisconsin Law Applies to the Hydes' Claims.

Plaintiffs argue that Wisconsin cases apply "two similar choice-of-law methods: the grouping-of-contacts analysis and the choice-influencing-factor analysis." (Pls. Resp. Br. at 3). The reason is that "Wisconsin law applies different analyses depending on whether the issue presented is a question of contract law or tort law." *McCraw v. Mensch*, 461 F. Supp. 2d 872, 877 (W.D. Wis. 2006) (describing contract "grouping-of-contacts" test and tort "choice-influencing-factors" test as "entirely different set[s] of factors"). The grouping-of-contacts test that Plaintiffs argue in their Response brief applies only for resolving conflicts questions raised as to a disputed contract, which is not an issue in this case. *Wisconsin Pharmacal Co., LLC v. Nebraska Cultures of California, Inc.*, 876 N.W.2d 72, 78 (Wis. 2016) (stating that Wisconsin has "adopted the grouping-of-contacts approach for resolving conflicts questions raised as to a disputed contract"); (Pls. Resp. Br., at 4 ("there is no contract at issue")).[2]

In support of their argument, Plaintiffs rely on *NCR Corp. v. Transp. Ins. Co.*, an insurance dispute involving "'tightly bound' issues of contract and tort." 823 N.W.2d 532, 535 (Wis. App. 2012) (quoting *Drinkwater v. Am. Family Mut. Ins. Co.*, 714 n.w.2D 568 (Wis. 2006)). *NCR Corp.* does not say that the grouping-of-contacts analysis applies in a case solely involving tort claims, however.[3] *See id.* Nor would such an application make sense, as the first four factors in the grouping-of-contacts analysis have any no relevance in a tort case. *See id.* (discussing place of contracting, place of negotiation of the contract,

[2] The grouping-of-contacts approach was adopted "for the resolution of questions pertaining to the validity and rights created by the provisions of a disputed contract." *Urhammer v. Olson*, 159 N.W.2d 688, 689 (Wis. 1968). Around the same time, the Wisconsin Supreme Court separately established the choice-influencing-factors approach for tort cases. *Heath v. Zellmer*, 151 N.W.2d 664, 671-73 (Wis. 1967).

[3] The bold language cited by Plaintiffs regarding whether tort law is "implicated" applies in the case of a contract dispute where tort law is also implicated, not a case solely involving tort claims. Contrary to Plaintiffs' characterization of the dispute, "tort law is [not] implicated in the *Hyde* case," (Pls. Resp. Br. at 5), rather it is the *sole* relevant legal framework here.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

place of performance of the contract, and location of subject matter of the contract). Plaintiffs thus use the incorrect test, claim that four of the five factors are irrelevant, and then argue that they should prevail based solely on the fifth factor, which they argue favors Nevada law. This argument, however, runs counter to longstanding Wisconsin tort choice-of-law jurisprudence, set out in the cases cited in Bard's Motion.

Plaintiffs' argument that "Wisconsin courts have consistently held the location of injury to be the most important factor," (Pls. Resp. Br. at 5), is not an accurate statement of the law. The Wisconsin Supreme Court's view of the choice-influencing-factors is that "[t]he importance of each factor will vary depending upon the specific facts presented in each case." *Beloit Liquidating Tr. v. Grade*, 677 N.W.2d 298, 307 (Wis. 2004). Plaintiffs also cite *Johnson v. Mylan, Inc.*, 107 F. Supp. 3d 967, 970 (E.D. Wis. 2015), arguing that the case "appl[ied] the grouping-of-contacts analysis and [found] that the case had the most significant relationship with Wisconsin." The description, however, is not accurate. The court did not apply the grouping-of-contacts analysis, and found that no analysis was needed because the parties did not dispute that Wisconsin substantive law applied. *Id.* at 970. The court in *Johnson* also reiterated that "[u]nder Wisconsin law, the law of the forum state governs a tort case unless it is clear that nonforum contacts are more significant." *Id.*

Thus, the cases that Plaintiffs cite in their Response brief are inapplicable to this case. Moreover, Plaintiffs did not address any of the cases cited in Bard's Motion, including *Schultz v. Glidden Co.*, No. 08-C-919, 2013 WL 4959007 (E.D. Wis. Sept. 13, 2013), a products liability case applying both the presumption in favor of Wisconsin law and the choice-influencing factors analysis. In *Schultz*, where the decedent was exposed to benzene-containing products while working and living in Wisconsin and then later moved to Florida where he was diagnosed with his illness and later died, the court found that applying Florida law would constitute "officious intermeddling" because "[t]he focus of this lawsuit is what happened in Wisconsin, not Florida." *Id.* at * 4. The same is true in Ms. Hyde's case: Ms. Hyde's filter was sold in Wisconsin, she was treated in Wisconsin

leading up to placement of the filter, and her filter was placed in Wisconsin. Like the decedent in *Schultz*, Ms. Hyde's move to another state (here, Nevada) was "a fortuitous happenstance, not a predictable result." *Id.*

For these reasons, and as discussed more fully in Bard's Motion, Wisconsin law should apply to Ms. Hyde's claims.

B. Plaintiffs' Strict Liability Design Defect Claim (Count III) Fails for Several Independent Reasons.

1. Plaintiff's IVC Filter Was Cleared by the FDA and Is Presumed Non-Defective.

Plaintiffs cite several orders issued by Judge Goodwin in the South District of West Virginia, to argue that Wisconsin's statutory presumption of no defect is inapplicable to 510(k) cleared devices, such as Bard's filters. (Pl. Resp. Br., at 9.) Bard submits that these cases are not controlling authority, and that they are incorrectly decided.

Wisconsin courts look to the statute's language, and if the meaning is plain, the inquiry typically ends there. *State v. Williams*, 852 N.W.2d 467, 472 (Wis. 2014). The "government rules" defense in Wisconsin's product liability statute provides that "[e]vidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or statement law or agency shall create a rebuttable presumption that the product is not defective." Wis. Stat. § 895.047(3)(b). Because Bard's filters were cleared by the FDA as part of the statutory and regulatory framework of 510(k) review, Bard's filters fall squarely within the plain meaning of Wisconsin's product liability statute.

Judge Goodwin, however, reasoned that the Wisconsin statute concerns whether a defect rendered a product "unreasonably dangerous," that the 510(k) clearance process "does not go to the safety of a product," and therefore the 510(k) framework does not amount to a "relevant standard" under the Wisconsin statute. *Williams v. Boston Sci. Corp.*, No. 2:12-CV-02052, 2016 WL 1448860, at *3 (S.D. W. Va. Apr. 12, 2016) (citations and quotations omitted). The language of the statute, however, discusses "relevant standards," not "relevant safety standards." And, as discussed in Bard's Motion

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

for Summary Judgment Regarding Preemption (Doc. 5396), "FDA's [510(k)] review process reflects a determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness.'" (Mot. for Summary Judgment (Doc. 5396), at 17 (quoting FDA 2010 Working Report); *see generally id.* (discussing the safety issues integral to the FDA's 510(k) framework). Thus, regardless of whether "safety" is necessary to qualify as "relevant standards, conditions, or specifications," the result is the same: Bard's IVC filters should be entitled to a presumption of non-defectiveness. As discussed below, Plaintiffs have not rebutted this presumption as to Ms. Hyde's filter.

2. Ms. Hyde's Alleged Filter Complications Were Inherent and Known Risks of IVC Filters.

Plaintiffs admit that the Society of Interventional Radiology reported in 2001 that IVC filters as a class were reported to migrate at rates up to 18%, fracture at rates up to 10%, perforate the IVC at rates up to 41% and tilt at rates from 5% to 50%. (Pls. Controverting Statement of Facts Regarding Plaintiffs Hyde ¶ 9.) Thus, these events are inherent to the characteristics of IVC filters as a whole, and Plaintiffs' strict liability design defect claims are barred under Wisconsin law. Wis. Stat. § 895.047(3)(d). In their Response, Plaintiffs do not dispute that the adverse events that Ms. Hyde experienced are inherent to the characteristics of IVC filters in general, and therefore Bard should be entitled to summary judgment.

Plaintiffs also argue that Bard's filters experience migration and perforation at much higher rates than other filters. Plaintiffs support this argument by taking internal complaint tracking data, assuming that the internal rates are correct, assuming that the internal rates should be multiplied by 100, and then comparing the resulting rates across devices. (Pls. Resp. Br. at 10.) Plaintiffs' math, however, is entirely made up. None of Plaintiffs' experts have opined about or endorsed these calculations. None of Plaintiffs' experts have opined that the resultant rates cited in Plaintiffs Response brief are, in fact,

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

reliable or accurate rates. And the rates are demonstrably inaccurate as discussed in the SIR Guidelines.[4] Again, summary judgment is appropriate.

3. Plaintiffs Lack Evidence of a Reasonable Alternative Design.

The G2X or Eclipse Filter that Ms. Hyde received was always cleared as an optional filter: the filter could be left in permanently or the filter could be percutaneously retrieved.[5] Plaintiffs claim that the Simon Nitinol Filter, which is a different product and is not an optional filter, is nonetheless a reasonable alternative design. But Plaintiffs cite no case law supporting such an argument and do not address the case law that Bard cited in its Motion. *See also, e.g., Burks v. Abbott Labs*, No. 08-3414 (JRT/JSM), 2010 WL 1576779, at *4 (D. Minn. Apr. 20, 2010) (rejecting liquid infant formula as an alternative design to a powdered infant formula); *Hosford v. BRK Brands, Inc*., 223 So.3d 199, 207 (Ala. 2016) (affirming judgment as a matter of law that "dual-sensor smoke alarms" are not reasonable alternative designs to "ionization smoke alarms"); *Caterpillar v. Shears*, 911 S.W.2d 379, 384-85 (Tex. 1995) ("A convertible can be made safer by fully enclosing the cab, but then it is just an ordinary car. . . . It is not rational, however, to impose liability in such a way as to eliminate whole categories of useful products from the market."); *Niedner v. Ortho-McNeil Pharm., Inc*., 58 N.E.3d 1080, 1087 (Mass. Ct. App. 2016) (rejecting that oral contraceptives are a feasible alternative design to a patch contraceptive); *Brockert v. Wyeth Pharms., Inc*., 287 S.W.3d 760, 770 (Tex. Ct. App. 2009) ("a safer alternative design must be one for the product at issue"). Plaintiffs' argument also ignores the testimony of Ms. Hyde's implanting physician who said that

[4] For example, Plaintiffs argue that the rate of migration for all filters is 0.8% (0.008% x 100), but the SIR Guidelines note that migration has been reported in up to 18% of filters, as Plaintiffs have admitted. Alternatively, if Plaintiffs' calculations are correct that the migration rate for Bard's G2/G2X Filters are 12.1%, then this rate still falls within the 18% rate cited in the SIR Guidelines. Either way, Plaintiffs' argument should fail.

[5] Plaintiffs argue that "the G2/G2X filter, as all Bard IVC filters, was submitted for clearance by the FDA as a permanent device." (Pls. Resp. at 16.) But that's not true for the G2X and Eclipse filter, one of which Ms. Hyde received. Both the G2X and Eclipse filters were submitted to the FDA for clearance as optional filters.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

retrieval of Ms. Hyde's filter was a possibility, and that he viewed the option to retrieve the Bard filter as a benefit (and a benefit not available for the Simon Nitinol Filter). (Henry Dep. Tr., 72:13-24; 89:7 to 90:19, attached as Exhibit A.) Thus, the Simon Nitinol Filter was not a reasonable alternative design to Ms. Hyde's Filter.

Plaintiffs argue in the alternative that adding caudal anchors "or any other feature that would prevent caudal migration" would be a reasonable alternative design to the G2/G2X Filter. (Pls. Resp. Br. at 17.) The portion of the record that Plaintiffs cite, however, is Dr. McMeeking's deposition testimony that Bard could have incorporated caudal anchors and penetration limiters sooner than it ultimately did (referring to design features ultimately incorporated in the Meridian Filter) *and also* "could have redesigned the filter configuration to try and find a better -- a better combination of -- of -- of phenomena that would improve the behavior of the filter in terms of the risks involved." (Pls. Resp. Br. at 17 (citing SOF paras. 168-70).) This is not a reasonable alternative design for several reasons. First, Plaintiffs selectively cite only a portion of Dr. McMeeking's testimony, and the full testimony does not specify all of the changes should have been made to the G2/G2X Filters to eliminate the alleged design defect. Second, even if Plaintiffs could limit the alternative design to inclusion of the caudal anchors that Bard incorporated into the Meridian Filter, Plaintiffs claim (and Dr. McMeeking also opines) that the Meridian Filter is still defectively designed and as such cannot be an alternative design because it does not cure the alleged defect. Third, Plaintiffs do not say how caudal anchors would have cured the alleged defect in the Bard filter that allegedly caused Ms. Hyde's damages. They argue, without any citation to the record, that "[i]t is the filter's propensity to tilt, leading to perforation, and vice versa that constitutes the manifestation of the device's design defect." (Pls. Resp. Br., at 17.) But Plaintiffs do not claim that incorporation of these design features would have cured the alleged defect in Bard's filter.

For each of these reasons, Plaintiffs have not identified a reasonable alternative design, and the Court should grant summary judgment on their design defect claims.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

C. Plaintiffs' Strict Liability Failure-To-Warn Claim (Count II) Fails Because of Wisconsin's Statutory Defense and for Lack of Evidence.

As discussed above, Bard thinks that compliance with the 510(k) program entitles it to a presumption that the warnings contained in the Instructions for Use ("IFU") were not defective; and that plaintiffs' strict liability failure-to-warn claim is barred because the alleged damage to Ms. Hyde was caused by a known and inherent characteristic of Bard's filter. Wis. Stat. § 895.047(3)(b), (d).

Moreover, an element of a strict liability failure-to-warn claim is proof of a reasonable alternative warning that would have rendered Bard's filter safe. *Lexington Ins. Co. v. Whesco Grp.*, Inc., No. 11-CV-598-BBC, 2013 WL 4454959, at *8 (W.D. Wis. Aug. 16, 2013). Plaintiffs do not identify a reasonable alternative warning anywhere in their Response brief, however. Rather, they argue that "[a] reasonable alternative warning would feature all the information that Bard knew regarding the G2/G2X's performance and propensity to malfunction at a higher rate than other Bard filters and competitive filters, rather than the general, inadequate warning found in the IFU." (Pls. Resp. Br., at 21.) Plaintiffs do not define what language this boils down to, however. They have not identified any case law supporting the level of specificity in the warning that they demand, they have not addressed the case law finding no such duty that Bard identified in its Motion, and they have not addressed the fact that no other IVC filter manufacturer provides comparative information in their IFUs. (Mot. at 15.) As discussed in greater detail in Bard's Reply in Support of Its Motion for Summary Judgment Regarding Plaintiffs' Jones, which Bard fully incorporates herein, there is no duty to provide such comparative warnings, and the Court should decline to impose one here. For each of these reasons, Plaintiffs' strict liability failure-to-warn claim fails.

D. Plaintiffs' Negligent Failure-To-Warn Claim (Count VII) Fails for Several Independent Reasons.

1. Under Wisconsin's Likely Adoption of the Learned Intermediary Doctrine and the Sophisticated User Doctrine, Bard Had No Duty To Warn.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

In their Response brief, Plaintiffs cite several Wisconsin cases in which the court refused to apply the learned intermediary doctrine in the context of prescription drug cases, not prescription medical device cases. (Pls. Resp. at 18.) These courts did not offer any reason to believe that the Wisconsin Supreme Court would not adopt the learned intermediary doctrine if presented with the issue.[6] Indeed, the vast majority of states apply some version of the doctrine. *See Tyree v. Boston Sci. Corp.*, 56 F. Supp. 3d 826, 828 n.3 (noting that the state supreme courts of thirty-five states (including the District of Columbia) have adopted the learned intermediary doctrine or favorably cited its application, and noting an additional thirteen states (including Wisconsin) in which state intermediate courts or federal courts have applied the doctrine or predicted that the highest state court would adopt it). And the rationale for applying the learned intermediary doctrine in the context of prescription implantable medical devices is particularly strong because patients rely on the experience and expertise of their treating physician about the medical need for a device based on the individualized circumstances of the patient. Accordingly, the Court should apply the learned intermediary doctrine in Ms. Hyde's case.[7]

Bard's Motion also discussed the applicability of the sophisticated user doctrine, whereby Bard had no duty to warn about the risks that came to pass in Ms. Hyde because they were known risks associated with IVC filters generally, including with Bard filters.

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[6] *See Maynard v. Abbott Labs.*, No. 12–C–0939, 2013 WL 695817, at *5 (E.D. Wis. Feb. 26, 2013) (stating, without explanation, in a case involving a drug prescribed for treating arthritis that "Wisconsin does not apply the learned intermediary doctrine"); *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009) (declining to apply the doctrine without some indication that the Wisconsin Supreme Court would do so and where deciding question of doctrine's applicability was unnecessary to determine the outcome); *Peters v. AstraZeneca, LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006) (declining to "create Wisconsin law" by adopting doctrine in case involving drug prescribed for treatment of acid reflux).

[7] Plaintiffs mention multiple times in their Response brief that "Bard concedes that they had a duty to advise both doctors and patients of a number of significant risks," but Bard made no such concession, which is counter to the overwhelming weight of authority.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

(Mot. at 13-14.) Plaintiffs do not address Bard's argument in their Response, but they do admit that since 2001 the medical literature discussed the precise complications that Ms. Hyde experienced; that, before Ms. Hyde was treated with a Bard filter, several articles in the medical literature discussed the same complications that came to pass with Ms. Hyde's filter occurring with the Bard G2 Filter; and that, six months before Ms. Hyde was treated with a Bard filter, the FDA issued a Safety Communication, which noted that "known long term risks associated with IVC filters" included the same risks that came to pass with Ms. Hyde's filter. (Pls. Controverting Statement of Facts Regarding Plaintiffs Hyde paras. 9-13.) Accordingly, the Court should find that Bard had no duty to warn under the sophisticated user doctrine, and grant summary judgment on Plaintiffs' negligent failure-to-warn claim.

2. Bard's Warning Were Adequate as a Matter of Law.

Although Plaintiffs admit that the IFUs for Bard's filters warn of the precise risks of complication that came to pass in Ms. Hyde, they nonetheless claim that Bard's warnings were inadequate. Plaintiffs argue for several pages about alleged information contained in Bard documents, but they never identify what precise information/language Bard's warnings should have contained. Nor do Plaintiffs cite any case law finding a duty to include the type of information that they generally demand, such as "[Bard] failed to warn of the ***increased*** risk of adverse events when compared to the SNF and competitor filters." (Pls. Resp. Br., at 21 (emphasis in original).) Finally, Plaintiffs do not address the case law cited in Bard's Motion that found warnings adequate as a matter of law in similar contexts as Ms. Hyde's case; nor do they address the case law cited in Bard's Motion that rejected arguments that manufacturers had a duty to include comparative rate information in their warnings. As discussed in Bard's Motion, the IFU's warnings clearly conveyed the risks of Bard's filter, and therefore the Court should find the warnings adequate as a matter of law.

3. Any Alleged Failure to Warn Was Not the Proximate Cause of Plaintiffs' Injuries.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

As Bard discussed in its Motion, an element of Plaintiffs' failure-to-warn claim is that a purported proper warning would have caused a different product to be used, thereby avoiding the plaintiff's alleged injuries. (Mot. at 16-17.) Plaintiffs have no evidence to satisfy this element of their claim, however, and they do not address Bard's argument in their Response. As such, Plaintiffs' failure-to-warn claim fails as a matter of law.

E. Plaintiffs' Breach of Implied Warranty Claim (Count XI) Fails Because Wisconsin Does Not Recognize the Cause of Action in Product Liability Cases.

Plaintiffs do not address Bard's argument in their Response. As discussed in Bard's Motion, the Court should grant summary judgment on this claim.

F. Plaintiffs' Negligent and Fraudulent Misrepresentation/Concealment Claims (Counts VIII, XII, XIII) and Claim for Violation of Wisconsin Law Claim (Count XIV) Fail as a Matter of Law Because Plaintiffs Cannot Prove the Essential Elements of Reliance or Causation.

Plaintiffs acknowledge that each of these causes of action require them to prove that either they or Dr. Henry acted in reliance upon a false representation by Bard or a material factual omission by Bard. (Pls. Resp. Br. at 22.) Plaintiffs argue that they satisfy the reliance element of their claims because Dr. Henry relied on the FDA and the FDA relied on false representations/omissions by Bard. Plaintiffs' logic seems to be that Bard made misrepresentations and concealed information from the FDA; the FDA acted in reliance upon these false representations or material factual omissions; the FDA would not have cleared Bard's G2X or Eclipse Filter if not for reliance on Bard's false representations or material factual omissions; and therefore "Dr. Henry was relying on the untruthful and misleading ways Bard got its products cleared by the FDA's 510(k) process." (Pls. Resp. Br. at 24.) Plaintiffs do not cite a single case in support of their argument, and Bard cannot find a single case supporting Plaintiffs' argument.

Indeed, Plaintiffs appear to be making a thinly veiled fraud-on-the-FDA argument, which is preempted. *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348, 350 (2001) (holding that, under the Supremacy Clause of the United States Constitution, state law claims asserting an alleged fraud on the FDA "conflict with, and are therefore

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000

impliedly pre-empted by federal law"; therefore, "state-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud [as provided by federal statutes]"); *Estes v. Lanx, Inc*., 660 F. Appx. 260, 262 (5th Cir. 2016) (affirming that fraudulent concealment claim is impliedly preempted under Buckman); *Lofton v. McNeil Consumer & Specialty Pharm*., 672 F.3d 372, 379-81 (5th Cir. 2012) (finding that a fraud-on-the-FDA argument to rebut the presumption of non-liability contained in CPRC section 82.007(b)(1) was preempted, noting that any other result would "allow the state court to interject varying views on what disclosures are sufficient"); *In re Incretin-Based Therapies Prod. Liab. Litig*., 142 F. Supp. 3d 1108, 1130–31 (S.D. Cal. 2015) ("A reevaluation of scientific data or a judicial challenge to the accuracy of the FDA's conclusions would disrupt the 'delicate balance of statutory objectives' the Buckman Court sought to preserve."); *Webster v. Pacesetter, Inc*., 259 F. Supp. 2d 27, 36 (D.D.C. 2003) (citing *Buckman*, "plaintiffs cannot bootstrap their arguments regarding defendant's alleged failure to report and investigate adverse incidents to the FDA into a defective warning case").

Because Plaintiffs have cited no authority to support their argument that a fraud on the FDA can be used to satisfy the reliance element of their claims; and because such an argument appears to be preempted under *Buckman*, the Court should grant summary judgment.

G. Plaintiffs' Claim for Failure to Recall/Retrofit (Count VI) Fails Because Wisconsin Does Not Recognize This Claim as an Independent Cause of Action.

Plaintiffs do not address Bard's argument in their Response. As discussed in Bard's Motion, the Court should grant summary judgment on this claim.

CONCLUSION

For these reasons, Bard respectfully requests that this Court grant Bard's Motion for Partial Summary Judgment.

RESPECTFULLY SUBMITTED this 25th day of October, 2017.

By: s/ Richard B. North, Jr.

Richard B. North, Jr. (admitted *pro hac vice*)
Georgia Bar No. 545599
Matthew B. Lerner (admitted *pro hac vice*)
Georgia Bar No. 446986
Nelson Mullins Riley & Scarborough LLP
201 17th Street, NW / Suite 1700
Atlanta, GA 30363

James R. Condo
Amanda C. Sheridan
One Arizona Center
400 E. Van Buren, Suite 1900
Phoenix, Arizona 85004-2202

Attorneys for C. R. Bard, Inc. and Bard Peripheral Vascular, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on October 25, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

s/ Richard B. North, Jr.

Nelson Mullins Riley & Scarborough L.L.P.
201 17th Street NW, Suite 1700
Atlanta, GA 30363
(404) 322-6000